UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Novo Nordisk, Inc., and Novo Nordisk A/S,

Plaintiffs,

v.

Paddock Laboratories, Inc.,

Defendant.

Civil No. 10-2199 (DWF/JJK)

MEMORANDUM OPINION AND ORDER

Aric H. Wu, Esq., Ashley E. Johnson, Esq., Austin V. Schwing, Esq., George A. Nicoud, III, Esq., Josh A. Krevitt, Esq., Michael A. Sitzman, Esq., Wayne M. Barsky, Esq., and M. Sean Royall, Esq., Gibson, Dunn, Crutcher LLP; Chad Drown, Esq., Christopher J. Burrell, Esq., Kenneth A. Liebman, Esq., Faegre & Benson LLP; and W. Todd Miller, Esq., Baker & Miller PLLC, counsel for Plaintiffs.

Rachel K. Zimmerman, Esq., Merchant & Gould PC; and Daniel G. Brown, Esq., Gina R. Gencarelli, Esq., Nicole W. Stafford, Esq., Seth C. Silber, Esq., and Tonia Ouellette Klausner, Esq., Wilson, Sonsini, Goodrich & Rosati PC, counsel for Defendant.

INTRODUCTION

This matter is before the Court on a Motion to Stay Litigation of Patent Claims and Defenses Pending Appeal brought by Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (together, "Novo Nordisk") and a Motion for Judgment on the Pleadings Based on Collateral Estoppel and/or Summary Judgment of No Infringement brought by Defendant Paddock Laboratories, Inc. ("Paddock"). For the reasons set forth below, the Court grants in part and denies in part Paddock's motion and denies Novo Nordisk's motion.

BACKGROUND

Novo Nordisk holds United States Patent No. 6,677,358 (the "'358 Patent"), which is directed to and claims a pharmaceutical composition that includes repaglinide in combination with metformin.[1] (Compl. ¶¶ 11, 12 & Ex. A.) Novo Nordisk also holds the FDA-approved New Drug Application ("NDA") for repaglinide, and it manufactures and sells repaglinide under the brand name PRANDIN®. (Compl. ¶ 13.)

In 2005, Caraco Pharmaceutical Laboratories, Ltd., ("Caraco") submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking approval to engage in the commercial manufacture and sale of a generic form of repaglinide tablets prior to the expiration of the '358 Patent. On June 9, 2005, Novo Nordisk sued Caraco for infringement of the '358 Patent in the United States District Court for the Eastern District of Michigan (the "Michigan court"). (Decl. of Daniel G. Brown ("Brown Decl.") ¶ 5, Ex. 1 (*Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, No. 05-40188 (E.D. Mich. 2005) (the "Michigan Action")).)

In May 2010, Novo Nordisk filed this action alleging infringement of the '358 Patent and seeking a declaration that Novo Nordisk has not violated the Antitrust Laws of the United States, 15 U.S.C. § 1, *et seq*. (Compl. ¶¶ 1, 45, 50.) Novo Nordisk's patent infringement claims are based on Paddock's submission of its ANDA to the FDA seeking approval to engage in the commercial manufacture and sale of a generic form of

[1] Combination therapy with repaglinide and metformin is a treatment for Type 2 diabetes. (Compl. ¶ 10.)

repaglinide. (Compl. ¶¶ 31, 45.) Paddock filed an answer, several affirmative defenses (including the defenses of invalidity due to obviousness and unenforceability due to patent misuse), and six counterclaims (including claims for declarations that the '358 Patent is invalid under the doctrine of obviousness and unenforceable for patent misuse, as well as counterclaims for non-infringement and monopolization).

In June and August 2010, the district court in the Michigan Action held trial on Caraco's counterclaims for invalidity and unenforceability of the '358 Patent. On January 19, 2011, the Michigan court issued a decision ruling: (1) that the '358 Patent is not invalid because of anticipation; (2) that the '358 Patent is invalid because of obviousness; and (3) that the '358 Patent is unenforceable because of inequitable conduct. *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, __ F. Supp. 2d __, No. 05-40188, 2011 WL 163996, at *39 (E.D. Mich. Jan. 19, 2011) (the "Michigan Decision"). Judgment was entered and Novo Nordisk appealed from the judgment to the Federal Circuit Court of Appeals. (Decl. of Michael A. Sitzman ("Sitzman Decl.") ¶ 3, Ex. B.)

Presently before the Court are: (1) Novo Nordisk's motion to stay litigation of all patent claims and defenses in this action pending the Federal Circuit's resolution of Novo Nordisk's appeal in the Michigan Action; and (2) Paddock's motion for judgment on the pleadings on Novo Nordisk's patent infringement claim under principles of collateral estoppel.

DISCUSSION

I. Motion to Amend

Paddock seeks, as a preliminary matter, leave to amend its Answer to assert the defenses of collateral estoppel and unenforceability of the '358 Patent due to inequitable conduct.[2] Paddock bases its request on facts revealed in the Michigan Decision. Paddock asserts that the amendment would eliminate any question as to whether collateral estoppel applied to preclude Novo Nordisk's pursuit of its patent claim in this action. Paddock further asserts that good cause has been shown and that there is no undue delay, bad faith, or dilatory motive on its part. Novo Nordisk does not offer arguments opposing Paddock's request to amend its Answer.

There is no dispute that the deadline to amend pleadings in this case has passed. Therefore, the "good cause" standard of Rule 16(b) applies to Paddock's request for leave to amend. *See Freeman v. Busch*, 349 F.3d 582, 589 (8th Cir. 2003); *Birchwood Labs., Inc. v. Battenfeld Techs., Inc.*, 762 F. Supp. 2d 1152, 1154 (D. Minn. 2011). This case is in an early stage of litigation. At the time Paddock filed its motion, neither party had produced documents and no depositions had been noticed or taken. (Brown Decl. ¶¶ 15-23.) Paddock represents that the facts underlying the inequitable conduct defense were unknown prior to the Michigan Decision. Moreover, the record does not suggest

[2] Paddock attaches its proposed Second Amended Answer and Counterclaims to the the Brown Declaration. (Brown Decl. ¶ 14, Ex. 10.)

any undue delay or bad faith on the part of Paddock. Therefore, the Court concludes that good cause exists and grants Paddock's request to amend its Answer.

II. Motion for Judgment on the Pleadings

A party may move for judgment on the pleadings at any point after the close of pleadings but early enough to avoid a delay of trial. Fed. R. Civ. P. 12(c). A court evaluates a motion for judgment on the pleadings under the same standard as a motion brought under Rule 12(b)(6). *See Ashley County v. Pfizer*, 552 F.3d 659, 665 (8th Cir. 2009); *Westcott v. City of Omaha*, 901 F.2d 1486, 1488 (8th Cir. 1990).

In deciding a motion to dismiss under Rule 12(b)(6), a court assumes all facts in the complaint to be true and construes all reasonable inferences from those facts in the light most favorable to the complainant. *Morton v. Becker*, 793 F.2d 185, 187 (8th Cir. 1986). In doing so, however, a court need not accept as true wholly conclusory allegations, *Hanten v. School District of Riverview Gardens*, 183 F.3d 799, 805 (8th Cir. 1999), or legal conclusions drawn by the pleader from the facts alleged. *Westcott*, 901 F.2d at 1488. A court may consider the complaint, matters of public record, orders, materials embraced by the complaint, and exhibits attached to the complaint in deciding a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure. *Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999).

To survive a motion to dismiss under Rule 12(b)(6), a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Although a complaint need not contain "detailed factual allegations," it must contain facts with enough specificity "to raise a right to relief

above the speculative level." *Id.* at 555. As the United States Supreme Court recently reiterated, the "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements," will not pass muster under *Twombly*. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citing *Twombly*, 550 U.S. at 555). In sum, this standard "calls for enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of [the claim]." *Twombly*, 550 U.S. at 556. The issue of whether collateral estoppel applies is properly resolved on a motion for judgment on the pleadings. *Blonder-Tongue Labs., Inc. v. Univ. of Illinois Found.*, 402 U.S. 313, 348 (1971).

Paddock asserts that under principles of collateral estoppel it is entitled to judgment on the pleadings on Novo Nordisk's patent infringement claim. Paddock argues that it is entitled to the full enforcement of the Michigan court's determinations that the '358 Patent is unenforceable due to Novo Nordisk's inequitable conduct and that claim 4 of the '358 Patent is invalid for obviousness.

Novo Nordisk opposes Paddock's motion for judgment on the pleadings and asserts that the prudent course would be for the Court to exercise its discretion and stay this action pending appeal.[3] Novo Nordisk contends a stay is warranted here because

[3] The Court has the inherent power to stay an action to control its docket, conserve judicial resources, and provide a just determination of the case. *See Lunde v. Helms*, 898 F.2d 1343, 1345 (8th Cir. 1990) (*citing Landis v. N. Am. Co.*, 299 U.S. 248, 254-55 (1936)). In determining whether to issue a stay, the Court considers (1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay will simplify the issues; and (3) whether discovery is complete and whether a trial date has been set. *VData, LLC v. AETNA, Inc.*, Civ. No. 06-1701, 2006 WL 3392889, at *5 (D. Minn. Nov. 21, 2006).

there is uncertainty regarding the validity of the Michigan Decision and questions regarding the court's jurisdiction in the Michigan Action.

The determinations of patent invalidity and unenforceability are both entitled to collateral estoppel effect in suits by the patentee against other defendants. *Blonder-Tongue*, 402 U.S. at 349-50. *See also Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1382 (Fed. Cir. 1999) (affirming the application of collateral estoppel based on the judgment of invalidity and unenforceability).[4] Under the doctrine of collateral estoppel, Novo Nordisk cannot relitigate the merits of the holdings in the Michigan Decision in this Court if the following requirements are met:

> (1) the party sought to be precluded in the second suit must have been a party, or in privity with a party, to the original lawsuit; (2) the issue sought to be precluded must be the same as the issue involved in the prior action; (3) the issue sought to be precluded must have been actually litigated in the prior action; (4) the issue sought to be precluded must have been determined by a valid and final judgment; and (5) the determination in the prior action must have been essential to the prior judgment.

Robinette v. Jones, 476 F.3d 585, 589 (8th Cir. 2007) (quotation omitted).

There is no dispute that Novo Nordisk was a party in the Michigan Action and that the court in the Michigan Action entered a judgment of invalidity and unenforceability of the '358 Patent. Specifically the court in the Michigan Action held that the '358 Patent is unenforceable because of inequitable conduct in its prosecution and that claim 4 of the

[4] The Federal Circuit Court of Appeals has explained that "[i]n *Blonder-Tongue* . . . the Supreme Court ruled that once the claims of a patent are held invalid in a suit involving one alleged infringer, an unrelated party who is sued for infringement of those claims may reap the benefit of the invalidity decision under principles of collateral estoppel." *Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1577 (Fed. Cir. 1994).

'358 Patent is invalid for obviousness over the prior art. The issues regarding the invalidity and unenforceability of the '358 Patent are the same issues that are presented in this action. Both Paddock here and Caraco in the Michigan Action have asserted the defenses of obviousness and that the '358 Patent is unenforceable due to Novo Nordisk's inequitable conduct. Further, there is no dispute that the issues regarding the invalidity and unenforceability of the '358 Patent in the Michigan Action were actually litigated. Judgment in the Michigan Action was entered after an 11-day trial and the parties' post-trial briefing on those issues. Finally, the issues regarding the invalidity and unenforceability of the '358 Patent were essential to the judgment in the Michigan Action. The Michigan court's determination of inequitable conduct was the sole basis for the determination that the '358 Patent is unenforceable, and the determination of obviousness was the sole basis for the determination of invalidity. Based on the above, the Court concludes that the requirements for collateral estoppel have been met.[5]

Without disputing that the requirements for collateral estoppel have been met, Novo Nordisk asserts that the case should be stayed pending its appeal of the judgment in the Michigan Action to the Federal Circuit. It is well-settled, however, that for purposes

[5] Under *Blonder-Tongue*, a prior judgment will not have a collateral estoppel effect if a patentee can demonstrate that it did not have a full and fair opportunity to litigate. 402 U.S. at 332-34. In determining whether a patentee has had a full and fair opportunity to litigate an issue in a prior case, the Court considers factors such as choice of forum, incentive to litigate, whether the court employed the correct legal standard, whether the trier of fact "wholly failed to grasp the technical subject matter and issues in suit," and whether the patentee, without its fault, was deprived of crucial evidence in the first suit. *Blonder-Tongue*, 402 U.S. at 333. Based on the record before it, the Court concludes that none of these factors support re-litigating the issues of validity and unenforceability.

of collateral estoppel, finality attaches at the time of entry of judgment and a pending appeal does not bar the preclusive effect of the judgment. *See, e.g.*, *In re Ewing*, 852 F.2d 1057, 1060 (8th Cir. 1988); *Pharmacia*, 170 F.3d at 1381. Despite this, Novo Nordisk contends that the pending appeal in the Michigan Action and the Federal Circuit's decision in *Therasense, Inc. v. Becton, Dickinson and Co.*, __ F.3d __, No. 2008-1511, 2008-1512, 2008-1514, 2008-1505, 2011 WL 2028255 (Fed. Cir. May 25, 2011), justify deferring a decision on collateral estoppel and instead support the issuance of a stay.

First, Novo Nordisk argues that there is substantial uncertainty regarding the validity of the decision in the Michigan Action and whether the court in the Michigan Action had jurisdiction to enter judgment. In support, Novo Nordisk points out that a district court in New Jersey, in a case involving the same patent and ANDA for generic repaglinide, concluded that it lacked jurisdiction to decide the merits of the patent dispute. *Novo Nordisk Inc. v. Mylan Pharms. Inc.*, C.A. No. 09-2445, 2010 WL 1372437, at *7-13 (D.N.J. Mar. 31, 2010). Novo Nordisk argues that the New Jersey decision is inconsistent with the court's exercise of subject matter jurisdiction in the Michigan Action, and therefore that the decision in the Michigan Action should not be given preclusive effect. In the same vein, Novo Nordisk contends that the Supreme Court may be addressing the alleged jurisdictional defect because, in the Michigan Action, Caraco petitioned the Supreme Court for a writ of certiorari on an interlocutory appeal involving the scope of the Hatch-Waxman Act and Novo Nordisk has opposed the

petition on multiple grounds, including the alleged absence of federal jurisdiction. (Decl. of Aric H. Wu ¶¶ 8-10, Exs. D-F.)

The record indicates that Novo Nordisk had the opportunity to litigate the issue of subject matter jurisdiction in the Michigan Action. Indeed, Novo Nordisk made a motion to dismiss its own patent claims for lack of subject matter jurisdiction at trial in the Michigan Action. (Decl. of Gina R. Gencarelli ("Gencarelli Decl.") ¶ 6, Ex. B at 8.) The Michigan court denied the motion to dismiss and held that jurisdiction existed. (*Id*.) Novo Nordisk has not demonstrated that the Michigan court's exercise of jurisdiction was "seriously defective." *See Blonder-Tongue*, 402 U.S. at 333. Therefore, the Court respectfully declines to consider Novo Nordisk's jurisdictional argument.

Second, Novo Nordisk asserts that the Federal Circuit's *en banc* decision in *Therasense*, rejects the standards of both materiality and intent that were applied by the Michigan court with respect to its finding of inequitable conduct.[6] Novo Nordisk asserts that it would therefore be inequitable to give collateral estoppel effect to the judgment in the Michigan Action. Paddock asserts that the *Therasense* court affirmed the existing standard for determining intent and announced a standard for materiality that is lower than the standard applied in the Michigan Action. Thus, Paddock asserts that the

[6] In its opposition to Paddock's motion for judgment on the pleadings, Novo Nordisk originally noted that an *en banc* decision of the Federal Circuit in *Therasense* was anticipated. On May 25, 2011, the Federal Circuit issued its *en banc* decision. *Therasense*, 2011 WL 2028255 (Fed. Cir. May 25, 2011). The parties filed supplemental letter briefs addressing the *Therasense* decision.

Therasense decision actually supports the entry of immediate judgment on the basis of collateral estoppel.

In *Therasense,* the Federal Circuit revisited the standards for both materiality and intent with respect to the inequitable conduct defense, and explained:

> [T]he standards for intent to deceive and materiality have fluctuated over time. In the past, this court has espoused low standards for meeting the intent requirement, finding it satisfied based on gross negligence or even negligence. This court has also previously adopted a broad view of materiality, using a "reasonable examiner" standard . . . . Further weakening the showing needed to establish inequitable conduct, this court then placed intent and materiality together on a "sliding scale." . . .
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> This court embraced these reduced standards for intent and materiality to foster full disclosure to the PTO. This new focus on encouraging disclosure has had numerous unforeseen and unintended consequences. . . .
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> . . .
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> This court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.

Therasense, __ F.3d __, 2011 WL 2028255, at *7-9 (citations and quotations omitted).

The Federal Circuit went on to explain the proper standards:

> To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO. A finding that the misrepresentation or omission amounts to gross negligence or negligence under a "should have known" standard does not satisfy this intent requirement. In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference. In other words, the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.
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> . . .

> Intent and materiality are separate requirements. A district court should not use a "sliding scale," where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa. Moreover, a district court may not infer intent solely from materiality. Instead, a court must weigh the evidence of intent to deceive independent of its analysis of materiality. Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive.
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> Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence. However, to meet the clear and convincing evidence standard, the specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence. Indeed, the evidence must be sufficient to require a finding of deceitful intent in the light of all the circumstances. Hence, when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found.
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> . . .
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> The absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive.
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> . . .
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> This court holds that, as a general matter, the materiality required to establish inequitable conduct is but-for materiality. When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. Hence, in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference. In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction.

(*Id*. at *9-10) (citations and internal quotation marks omitted).

The decision in the Michigan Action was issued prior to the recent ruling in *Therasense*. Novo Nordisk argues that the legal standards used in the Michigan Action are contrary to those now applicable under *Therasense*. The Court therefore examines the standards used by the court in the Michigan Action.

In concluding that the ’358 Patent is unenforceable due to inequitable conduct, the Michigan court focused on Novo Nordisk’s submission of the Sturis Declaration and the accompanying representations of patent attorney Dr. Richard Bork. The Michigan court concluded that both the Sturis Declaration and representations of Dr. Bork were “highly material” to the patentability of Claim 4 under a “clear and convincing standard.” *Novo Nordisk A/S v. Caraco*, __ F. Supp. 2d __, 2011 WL 163996, at *33-34 (¶¶ 142, 146). In addition, the Michigan court concluded that the examiner’s reliance on both the Sturis Declaration and Dr. Bork’s representations warrants the conclusion that the “but for” materiality test was satisfied. (*Id*.) With respect to intent to deceive, the Michigan court found that there was “clear and convincing evidence” justifying the inference that Sturis and Bork had the intent to deceive, and significantly that no reason other than an intent to deceive would be credible. (*Id*. at *35-36 (¶¶ 153-54) (noting an “intent to deceive is the ‘single most reasonable inference to be drawn from the evidence’”.) Because the court in the Michigan Action found clear and convincing evidence of both “but for” materiality and intent to deceive under the “single most reasonable inference” standard, the Michigan court’s conclusions appear to comport with the standards enunciated in *Therasense*. Thus, the Court discerns no reason to consider the judgment in the Michigan Action to be non-final or to decline to give the judgment collateral estoppel effect.

For all of the reasons stated above, the Court concludes that the factors required for the application of collateral estoppel apply to the judgment in the Michigan Action. Accordingly, the Court concludes that Novo Nordisk’s patent claims are precluded. In so holding, the Court also finds that the equities favor the entry of judgment as opposed to a

stay of the present action.[7] Thus, the Court also necessarily denies Novo Nordisk's motion to stay. The Court also denies Paddock's motion for summary judgment on Novo Nordisk's patent infringement claims as to claims 1, 2, 3, and 5 of the '358 Patent. Paddock claims that it is entitled to summary judgment on these claims because its accused product only contains one active ingredient, repaglinide. At the time of the briefing on the present motions, no document or deposition discovery had occurred and no claim construction had been performed. The Court concludes that Paddock's motion for summary judgment on these claims, therefore, is premature and denies the motion without prejudice to bring the motion again in the future.

CONCLUSION

Based on the files, records, and proceedings herein, and for the reasons set forth above, **IT IS ORDERED** that:

1. Novo Nordisk's Motion to Stay Litigation of Patent Claims and Defenses Pending Appeal (Doc. No. [76]) is **DENIED**.

[7] In opposition to Paddock's motion and in support of its motion to stay, Novo Nordisk submits that a stay would not unduly prejudice Paddock, but that a dismissal would cause substantial prejudice to Novo Nordisk. Novo Nordisk highlights that even though it could re-file its lawsuit against Paddock after a dismissal in this action if the judgment in the Michigan Action is ultimately reversed on appeal, it could not reinstate the statutory 30-month stay that is currently in place with the FDA. The Court concludes, on the record before it, that any prejudice to Novo Nordisk is outweighed by the prejudice that Paddock would suffer if its market entry is delayed. In addition, any harm to Novo Nordisk could be remedied by money damages.

2. Paddock's Motion for Judgment on the Pleadings Based on Collateral Estoppel and/or Summary Judgment of No Infringement (Doc. No. [86]) is **GRANTED IN PART** and **DENIED IN PART** as follows:

a. Paddock's request to file its Second Amended Answer and Counterclaim is **GRANTED**.

b. Judgment on the pleadings is entered in favor of Paddock on Novo Nordisk's patent infringement claim based on the collateral estoppel effect of the judgment of unenforceability of the '358 Patent in the Michigan Action.

c. Judgment on the pleadings is entered in favor of Paddock that claim 4 of the '358 Patent is invalid based on the collateral estoppel effect of the judgment of invalidity of claim 4 of the '358 Patent in the Michigan Action.

d. Paddock's motion for summary judgment for non-infringement of claims 1, 2, 3, and 5 of the '358 Patent is **DENIED**.

Dated: June 22, 2011

s/Donovan W. Frank
DONOVAN W. FRANK
United States District Judge